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EXAMINER	
HOEKSTRA, JEFFREY GERBEN	
ART UNIT	PAPER NUMBER
3736	
MAIL DATE	DELIVERY MODE
04/17/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/630,402	FLAHERTY, PATRICE	
	Examiner	Art Unit	
	Jeffrey G. Hoekstra	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7 and 9-32* is/are pending in the application.

4a) Of the above claim(s) *12-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9-11 and 24-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Notice of Amendment

1. In response to the amendments filed on 02/19/2009, amended claim(s) 1, 7, and 24 is/are acknowledged. The current rejections of the claim(s) 1-7, 9-11, and 24-32 is/are *withdrawn*. The following new and/or reiterated grounds of rejection are set forth:

2. The Examiner notes claims 9, 10, 31, and 32 do not appear currently amended as indicated in Applicant's remarks (see page 12 filed 02/19/2009).

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1-7, 9-11, and 24-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Propp (US 5,919,146) in view of Prager (US 4,257,416).

5. For claims 1, 2, 4, 5, 7, 10, 24, and 26, Propp discloses a multi-channel bodily-fluid handling device (as best seen in Figure 1), comprising *inter alia*:

- a main tubing segment (40) for the passage of bodily fluids (as best seen in Figure 1);
- an indicator unit (48 and 56) and an access port (30) disposed in fluid communication with said main tubing segment and in a branched relationship to each other (as best seen in Figure 1),

- wherein both the indicator unit and access port are associated with respective connective tubing conduits or legs (44 and 32, respectively) (as best seen in Figure 1),
- wherein said indicator unit comprises a fluid volumeter (48 and 56) having a chamber (48 and 56) adapted for indicating fluid volume (column 2 lines 7-11 and column 3 lines 36-58) (as best seen in Figure 1),
- wherein said indicator unit has a first end (the bottom end of 56 as best seen in Figure 1) disposed in fluid communication with said main tubing segment (as best seen in Figure 1) and a second end (the upper end of 48 as best seen in Figure 1) opposite the first end (as best seen in Figure 1), and
- wherein an air flow pathway (the internal fluid flow pathway of the fluid volumeter 48 and 56) (as best seen in Figure 1) extends through said fluid volumeter between said first and second ends (as best seen in Figure 1) and a bidirectional liquid flow pathway (the internal fluid flow pathway of the fluid volumeter 48 and 56) (as best seen in Figure 1) coincides with the air flow pathway between said first and second ends (as best seen in Figure 1);
- a clamp (74) operably engaging said main tubing segment for selectively blocking fluid; and
- an air-permeable liquid-impervious membrane (60) disposed in fluid communication with said fluid volumeter at said second end of said fluid volumeter (as best seen in Figure 1) (column 3 lines 36-41 and column 4 lines 11-21),

- wherein said fluid volumeter is disposed between said main tubing segment and said at least one air-permeable liquid-impervious membrane (as best seen in Figure 1) and allows bidirectional fluid movement between and through said fluid volumeter and said access port (as best seen in Figure 1).

6. For claims 3, 6, 9, and 11, Propp discloses a multi-channel bodily-fluid handling device wherein said indicator unit is disposed in removable fluid communication with said main tubing segment (as best seen in Figure 1) via a second clamp (64) or via disassembly .

7. For claims 25 and 31, Propp discloses a multi-channel bodily-fluid handling device, further comprising: a connector (46) (as best seen in Figure 1) disposed in fluid communication with said main tubing segment, disposed in removable fluid communication with said indicator unit via a third clamp (54) or via disassembly, and between said clamp and said indicator unit and said port (as best seen in Figure 1).

8. For claim 27, Propp discloses a multi-channel bodily-fluid handling device, further comprising: a collector conduit (68) disposed in fluid communication with said main tubing segment via said indicator unit tubing conduit and disposed in fluid communication with said indicator unit (as best seen in Figure 1).

9. For claim 28, Propp discloses a multi-channel bodily-fluid handling device wherein said indicator unit comprises a volumeter conduit (66) disposed in fluid communication with said collection conduit and disposed in fluid communication with said volumeter conduit.

10. For claim 29, Propp discloses a multi-channel bodily-fluid handling device, further comprising: a port (62) disposed between said collector and volumeter conduits.

11. For claims 30 and 32, Propp discloses a multi-channel bodily-fluid handling device, further comprising: said access port tubing conduit or leg disposed in fluid communication with said main tubing segment and in a branched relationship to a collector tubing leg (as best seen in Figure 1), and wherein said access port is disposed on said access tubing segment (as best seen in Figure 1).

12. For claims 1-7, 9-11, and 24-32, Propp discloses the multi-channel bodily-fluid handling device, as set forth and cited above, except for expressly disclosing

- (a) the fluid comprises blood;
- (b) the fluid volumeter and the access port are disposed in bidirectional fluid communication with the main tubing segment; and
- (c) the clamp operably engaging the main tubing segment and adapted to selectively block and unblock fluid flow in both directions therethrough.

13. For claims 1-7, 9-11, and 24-32, Prager teaches multi-channel blood aspiration and fluid infusion device (as best seen in Figure 1) configured for introducing fluids into a patient and permitting withdrawal of blood samples (Abstract), comprising *inter alia*:

- (a) the fluid comprises blood (Abstract);
- (b) a fluid volumeter (45) (column 3 line 60 – column 4 line 21) and an access port (34 or 38) (column 3 line 60 – column 4 line 21) are disposed in bidirectional fluid communication with a main tubing segment (16) (Abstract) (as best seen in Figure 1) (column 5 lines 39-45); and

- (c) a clamp (52) operably engaging the main tubing segment (as best seen in Figure 1) and adapted to selectively block and unblock fluid flow in both directions therethrough (Abstract, column 2 lines 12-19).

14. Thus for claims 1-7, 9-11, and 24-32, the claimed invention would have been obvious because the substitution of one bodily fluid management configuration and components thereof for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Because both Propp and Prager teach components and configurations of bodily-fluid management devices, it would have been obvious to one skilled in the art at the time of the invention to substitute one component or configuration of a bodily-fluid management device for the other to achieve the predictable results of providing an alternate configuration of a bodily fluid handling device to decrease patient discomfort by using a bodily fluid handling device permitting both aspiration and infusion.

Response to Arguments

15. Applicant's arguments filed 02/19/2009 have been fully considered but they are not persuasive. Applicant argues the rejection of claims 1-7, 9-11, and 24-32 under 35 U.S.C. 103(a) as being unpatentable over Propp in view of Prager.

16. Applicant argues Propp in view of Prager does not disclose, teach, and/or fairly suggest the following:

a) for claims 1-6, "a main tubing segment...an indicator unit and an access port disposed in bidirectional fluid communication with said main tubing segment in

branched relationship to each other..." because Propp limits movement of fluids unidirectionally and only under the influence of gravity and Prager does not provide any teaching, suggestion or motivation to a person of ordinary skill in the art to use the Propp device for bidirectional fluid movement to and from a patient;

b) for claims 1-6, "a main tubing segment.., a clamp operably engaging said main tubing segment mad adapted to selectively block and unblock flow of the fluids in both directions through said main tubing segment..." because Propp limits the blocking of fluids unidirectionally and only under the influence of gravity and Prager does not provide any teaching, suggestion or motivation to a person of ordinary skill in the art to use the Propp device for bidirectional fluid blocking;

c) for claims 7 and 9-11, "a main tubing segment...a blood volumeter having a first end disposed in fluid communication with said main tubing segment and a second end...at least one air-permeable and liquid-impermeable membrane disposed in fluid communication with said blood volumeter at said second end of said blood volumeter..." because the vent of Prager is provided in fluid communication with the volumeter at the first end rather than the second end and Prager does not provide any teaching, suggestion or motivation to a person of ordinary skill in the art to rearrange the vent position;

d) for claims 7 and 9-11, "a main tubing segment...a blood volumeter...disposed in fluid communication with said main tubing segment...an access port disposed in fluid communication with said main tubing segment in branched relationship to said blood volumeter...at least one air-permeable and liquid, impermeable membrane...allowing

bidirectional fluid movement between said blood volumeter and said access port" because Propp limits movement of fluids unidirectionally and only under the influence of gravity and Prager does not provide any teaching, suggestion or motivation to a person of ordinary skill in the art to use the Propp device for bidirectional fluid movement to and from a patient; and

e) for claims 24-32, "a main tubing segment...a blood volumeter having a first end disposed in fluid communication with said main tubing segment, a second end, an air flow pathway extending through said blood volumeter between said first end and said second end and a bidirectional liquid flow pathway coinciding with said airflow pathway between said first end and said second end.., at least one air-permeable membrane provided in fluid communication with said blood volumeter at said second end of said blood volumeter..." because Propp limits movement of air and fluids unidirectionally and the air and fluid pathways must be separate.

17. The Examiner disagrees, maintains the rejection as set forth and cited above, and in response notes the following:

18. In response to applicant's arguments (a) – (d) that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case

Applicant apparently mischaracterizes the nature of the obviousness type rejection, the obviousness type rejection is based upon the KSR substitution of one well-known bodily fluid management configuration and/or component for another and conversely not solely upon the TSM. See MPEP 2141.

19. In response to applicant's argument (a) that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "bidirectional fluid movement to and from a patient") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

20. In response to applicant's argument (a)-(e) that Propp limits movement and/or blocking of air and/or fluids unidirectionally and only under the influence of gravity and that the air and fluid pathways must be separate, the Examiner notes as broadly as claimed Applicant appears to rely heavily on the terms "fluid communication", air flow "pathway", and "bidirectional" liquid flow "pathway" for patentability. Absent any special definition in the instant Specification upon which Applicant does not appear to be relying, the claims and the terms therein are being given their broadest reasonable interpretation consistent with the plain meaning of the terms therein. As such the terms "fluid communication", air flow "pathway", and "bidirectional" liquid flow "pathway" may be reasonably defined as follows: "allowing for the passage of a liquid or gas", an air flow "path", and "a path allowing the flow of a liquid or gas in two directions", respectively. Although Propp teaches "limits movement and/or blocking of air and/or

fluids unidirectionally and only under the influence of gravity", Propp discloses and shows structure having two oppositely disposed ends having a lumen defined therebetween, wherein the lumen may be defined as a path for both air and fluid in both directions because there is no restriction to either flow thereof and therein. For example, the addition of liquid in one direction may necessitate the flow of fluid in the alternate direction. Furthermore, the liquid and air flow passageways as claimed appear to define abstract spaces for fluid transfer and as broadly as claimed do not imply nor necessitate the air and fluid pathways must be separate.

21. In response to applicant's argument (c) that the vent of Propp is provided in fluid communication with the volumeter at the first end rather than the second end, the Examiner notes Applicant apparently mischaracterizes the nature of the rejection. Propp is relied upon to disclose, in part, said indicator unit has a first end (the bottom end of 56 as best seen in Figure 1) disposed in fluid communication with said main tubing segment (as best seen in Figure 1) and a second end (the upper end of 48 as best seen in Figure 1) opposite the first end (as best seen in Figure 1), and wherein an air flow pathway (the internal fluid flow pathway of the fluid volumeter 48 and 56) (as best seen in Figure 1) extends through said fluid volumeter between said first and second ends (as best seen in Figure 1) and a bidirectional liquid flow pathway (the internal fluid flow pathway of the fluid volumeter 48 and 56) (as best seen in Figure 1) coincides with the air flow pathway between said first and second ends (as best seen in Figure 1) and an air-permeable liquid-impervious membrane (60) disposed in fluid communication with said fluid volumeter at said second end of said fluid volumeter (as

best seen in Figure 1) (column 3 lines 36-41 and column 4 lines 11-21). As broadly as claimed and under the broadest reasonable interpretation of the claims, the claimed limitations comprising "at least one air-permeable membrane provided at said second end of said indicator unit" are insufficient to structurally distinguish over the applied prior art.

Conclusion

22. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday 8am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey G Hoekstra/
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736